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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,327	12/01/2000	Glen Jorgensen	ZQI-102 US B-CON1	4739

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,327	JORGENSEN ET AL.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-55* is/are rejected.

7)☒ Claim(s) *37-55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/2006 has been entered.

Claims 37-55 are pending.

Claims 1-36 have been cancelled.

Claims 37-55 are presently under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Claim Objections

The claims 37-55 are objected to because the lines are crowded too closely together, making reading difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claims 37 and 53, as amended, recite "the system is closed to environmental contaminants." However, "the system is closed to environmental contaminants," does not have support in the specification, claims, or drawings, as originally filed. Applicants point to "the originally filed claims" and the disclosure "throughout the specification" to support the claim amendments. Originally filed claims 9, 30, and 33 recite the limitations "a system for processing cells maintained in a sterile environment" and "wherein said modules are constructed and arranged to prevent unwanted contaminations of said cells during said process." The limitations "to prevent unwanted contaminations of cells" and "a system for processing cells maintained in a sterile environment" have a different scope from that of the limitation "the system is closed to environmental contaminants." The limitation "to prevent unwanted contaminations of cells" means that cells may not be contaminated by a contact with, for example, bacteria, or be impure by admixing. The limitation "a system for processing cells maintained in a sterile environment" merely means the cells were maintained in a sterile environment; e.g. a plate or flask which has not been contaminated by bacteria, but not necessarily that the "processing system" was sterile nor that the "system" as a whole (e.g. incubator) was closed to environmental contaminants. The new limitation "the system is closed to environmental contaminants" has multiple meanings (*see* the rejection under 112, second paragraph), *e.g.*, the system does not contaminate the

environment, the system is enclosed, for example, in a sterile chamber, the system does not receive any input or receives only input of sterile components while the system is not in sterile environment, the system does not receive any input and does not produce any output, *etc.* For these reasons, the claims are rejected for reciting new matter.

Second Paragraph

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 37-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims were previously rejected because the limitation "the system is environmentally closed" recited in claims 37 and 53 was indefinite. Applicants amended claims that now recite "the system is closed to environmental contaminations" and stated that the amendments render the rejection moot.

In response, it is noted that the limitation "the system is closed to environmental contaminants" is vague and indefinite because it is not clear whether the system does not contaminate the environment or the environment does not contaminate the system. It is further unclear whether the system is closed to input/output from/to outside (*e.g.*, sample input/output, chemicals, contamination, *etc.*), closed into a sterile chamber with specific conditions, or whether the system is intended to be one which allows only input of sterile components. As the intended limitation is not clear, claims 37-55 are indefinite.

Claim 42, as amended, recites the limitation "the in-line filter" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 42 recite "a filter" in line 1, but does not recite "an in-line filter." As the intended limitation is not clear, claim 42 is indefinite.

Claims 54-55 recite the limitations "blood cells are erythrocytes" and "blood cells have genotypes A, B, or AB," respectively. It is not clear what structural/functional limitation of the instant system is intended by reciting a type of blood cells processed by the system. As the intended limitation is not clear, claims 54-55 are indefinite.

Claim Rejections - 35 USC § 103

Claims 37-41, 44-49, and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Inoue, US 5,153,828.

The claims were previously rejected over Hei and Inoue. Applicants argue that Hei does not disclose "a plurality of sensors all adapted to the control module and individually adapted to either the supply module, the processing module or the cell module, the cell module sensor comprises a weight sensor." Applicants argue that the weight sensor permits the device to accurately calculate and deliver the appropriate volume of reagents. Applicants conclude that Hei does not teach the instant invention and Hei's device cannot be adapted for the purpose described in the instant application. Applicants also argue that Inoue does not discloses processing of blood cells and that Inoue's weight sensor does not control the measured addition of reagents to react with blood cells.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (*i.e.*, a weight sensor for controlling the measured addition of reagents to react with blood cells) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). FP 07.37.08. Specifically, claims 37 and 53 recite "the cell module sensor comprising a weight sensor" and do not recite "a weight sensor for controlling the measured addition of reagents to react with blood cells" (*see* the applicants' arguments at page 5-6). The specification discloses that a cell module includes a first weight sensor (element 14) arranged to weigh red blood cells provided in a bag. The specification also discloses that a supply module includes a different (second) weight sensor (element 29) constructed to weigh fluids located in a supply module. Thus, the claims are interpreted to be directed to the first weight sensor; it is noted that the claims do not recite a second weight sensor.

In response to the argument that Hei does not disclose "a plurality of sensors," it is noted that Hei does disclose a plurality of sensors, and specifically a sensor calculating the volume and weight of fluids to be reinfused to a patient (col. 65, line 30-47). Hei discloses a system having sensors that are able to monitor and control several important parameters, *e.g.*, detecting contaminants and dangerous condition (col. 65, lines 30-47). Some sensors determine, control, and establish the required amount of components (*e.g.*, anticoagulant) and calculate the volume of replacement fluid (col. 65, lines 30-47). Further, Hei discloses that a computerized controller may be connected to various sensors that monitor volumes, concentration, and required amounts of fluids, contaminants, and the like (col. 66, lines 63-65). Also, Hei discloses using a

microprocessor for adding an appropriate amount of PASIII (in a liquid form) (col. 68, line 14-24). Thus, the examiner maintains that Hei discloses "a plurality of sensors all adapted to the control module and individually adapted to either the supply module, the processing module or the cell module."

To further answer applicants' arguments, it is noted that the specification discloses a supply module comprising bags of fluids that comprise reagents used for blood processing, wherein the specific volume of the reagents at specific concentration is mixed with blood. The specification discloses that the weight sensor of the supply module controls the volume of the reagents measured in "ml" and concentration measured in "g/l", but does not disclose controlling "weight" measured in weight units (*e.g.*, gram). The sensors disclosed by Hei also measure required amounts of components and calculate the volume of replacement fluid, as set forth above.

To answer the applicants' argument that Inoue does not discloses processing of blood cells, applicants are reminded that the rejection is made under 35 U.S.C. 103(a) over a combination of references, wherein Hei discloses cell processing (abstract). To further answer the arguments regarding the disclosure by Inoue, it is noted that Inoue discloses a weight sensor adapted to a cell module, wherein the weight sensor is arranged to weigh blood cells provided in a bag (col. 5, lines 21-55). Thus, Inoue does disclose "the cell module comprising a weight sensor." The argument that Inoue does not disclose "the weight sensor permits the device to accurately calculate and deliver the appropriate volume of reagents" is not persuasive, because this limitation is not recited in the instant claims, as set forth above.

Motivation to combine the references was provided in the previous office action.

For the reasons stated above, the rejection is maintained.

Claims 42-43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Inoue, US 5,153,828, as applied to claims 37-41, 44-49, and 51-54 above, and further in view of Matkovich, US 5,126,054.

Applicants argue that Matkovich does not disclose a plurality of sensors.

Applicants are reminded that the rejection is made under 35 U.S.C. 103(a) over a combination of references. The examiner maintains that Hei and Inoue disclose a plurality of sensors and a weight sensor, as set forth above. Therefore, the rejection of claims 42-43 and 50 over Hei, Inoue, and Matkovich is also maintained.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hei, US 6,544,727, in view of Inoue, US 5,153,828, as applied to claims 37-41, 44-49, and 51-54 above, and further in view of Hudak, US 5,641,637.

Claim 55 was previously rejected over Hei, Inoue, and Hudak. Applicants argue that Hudak does not disclose a plurality of sensors. Applicants further argue Hudak teaches the invention which is exactly opposite to the instant invention because the instant specification clearly describes a system for the removal of blood antigen, which is designed for the purpose of creating a universally histocompatible blood cell.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (*i.e.*, the removal of blood antigen, which is designed for the purpose of creating a universally histocompatible blood

cell) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is also noted that that a blood cell type which is processed by the instant system (*i.e.*, blood cells have genotypes A, B, or AB recited in claim 55) does not structurally or functionally limit the instant system (*see* the rejection under 112, second paragraph).

The examiner maintains that Hei and Inoue do disclose a plurality of sensor and a weight sensor, as set forth above. Therefore, the rejection of claim 55 over Hei, Inoue, and Hudak is also maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MM

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8/31/06